DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2015

Eisertech, LLC
Mr. Lukas Eisermann
Chief Executive Officer
1133 Columbia Street, Suite 107
San Diego, California, 92101

Re: K140348
Trade/Device Name: Interbody Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 25, 2015
Received: March 27, 2015

Dear Mr. Eisermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140348

Device Name
Interbody Cage

Indications for Use *(Describe)*
The Interbody Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary:

Date: April 21, 2015

Company: Eisertech, LLC
1133 Columbia Street
Suite 107
San Diego, California 92101

Contact: Lukas Eisermann
lukas@eisertech.com
888-262-2817x101

Type of 510(k) submission: Traditional

Trade Name: Interbody Cage

Common Name: Intervertebral FusionDevice with Bone Graft, Lumbar

Classification Name: Orthosis, spinal intervertebral fusion

Regulation Number: 21 CFR 888.3080

Device Classification: Class II

Product Code: MAX

Purpose of the Submission

The purpose of this special 510(k) is to gain clearance for additional implant sizes and material options.

Description of device

The Interbody Cage is offered in a variety of heights, widths, and lengths. The implants are manufactured from medical grade polyetheretherketone (PEEK) or titanium alloy. The devices are intended to be implanted either one device per level when used in the ALIF, Banana, or Lateral styles, and one or two devices per level when used in the PLIF/TLIF style.

Tantalum pins are embedded in the PEEK versions of the implants to help allow for radiographic visualization.

Indications for Use

The Interbody Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to

S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which as been cleared by the FDA for use in the lumbar spine.

Materials

The devices are manufactured either from medical grade PEEK (ASTM F2026) with tantalum radiographic markers (ASTM F560), or from titanium alloy (ASTM F136). The specific grades of PEEK used may be either Zeniva ZA-500 (Solvay) or Vestakeep 4iR (Evonik).

Predicate Devices

Primary Predicate:

Eisertech, LLC PLIF Cage (k113478)

Additional Predicates:

Titan Spine Endoskeleton (k083714)
Alphatec GLIF Cage (k090425)

Reference Predicates:

K7, LLC - K133126 - Lumbar Cages
Cogent Spine - K132738 - Lumbar Cage
DiFusion - K123969 - ALIF Cage
SpineWorks - K133340 - ALIF Cage

Technological Characteristics

The Interbody Cage geometry is similar to that cleared in k113478. The worst-case size testing submitted as part of k113478 applies to all devices that are part of this current submission.

The main material of construction is either PEEK (ASTM F2026) or titanium alloy (ASTM F136). When used, the PEEK may be either Zeniva ZA-500 supplied by Solvay Advanced Polymers, which is one of the materials approved in k113478, or Vestakeep i4R, supplied by Evonik, Inc, which is the new material option being requested.

Performance Data

The additional materials and sizes do not alter the performance of the device. The additional PEEK option is equivalent in mechanical properties. The devices

made from titanium alloy are substantially stronger than those made from PEEK. All additional sizes are larger in bearing footprint than the worst-case size tested for k113478. Additional testing (compression) per ASTFM F2077 verified that the addition of new materials did not introduce a new worst-case. Therefore, the subject Interbody Cage is substatially equivalent to its predicates.